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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,654	04/18/2000	James T Loch III	3525-74	8308
22466	7590	09/22/2004	EXAMINER	
ASTRA ZENECA PHARMACEUTICALS LP GLOBAL INTELLECTUAL PROPERTY 1800 CONCORD PIKE WILMINGTON, DE 19850-5437			STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/529,654

Applicant(s)

LOCH III ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 44-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-69 is/are allowed.
- 6) ☒ Claim(s) 44,47,49,51-53,55 and 56 is/are rejected.
- 7) ☒ Claim(s) 45,46,48,50 and 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## Detailed Action

Claims 44-69 are pending in the application.

### *Continued Prosecution Application*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on June 30, 2004 has been entered.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 52, the phrase "according to any one of claim 51" is unclear since there is only one dependent claim listed. It is suggested that the phrase be changed to "according to claim 51".

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44, 47, 49, 51, 53, 55 and 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,110,914 and claims 1-8 and 11 of U.S. Patent No. 6,706,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in the claims of each of the patents. See formula I in claim 1 in column 37, and the compound in column 38, lines 56-57 under claim 8 of '914; and formula I in claim 1 in column 35 and the compound in column 37, lines 3-4 under claim 9 of '878.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating psychotic disorders).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, psychotic disorders. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44, 47, 49, 51, 53, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. {U.S. Pat. 6,110,914}.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim spiroazabicyclic heterocyclic compounds. Phillips et al. teach spiroazabicyclic heterocyclic compounds that are structurally similar to the instant claimed compounds. Note especially the compounds in column 3, lines 42-43; and in column 4, lines 23-24.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally

similar compounds would possess similar activity (e.g., treating psychotic disorders).

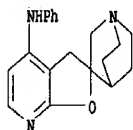
One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, psychotic disorders. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

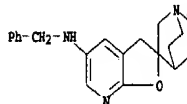
Applicants' arguments filed June 30, 2004 have been fully considered. Applicants argue that a *prima facie* case of obviousness has not been established. Applicants argue that Phillips et al. only provide for single specie of RN 220100-73-2 and RN 220100-57-2 (both shown below) but the reference does not provide any motivation or suggestion to make the instant claimed compounds.



RN 220100-73-2 REGISTRY  
CN Spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridin]-4'-amine,  
N-phenyl- (9CI) (CA INDEX NAME)  
FS 3D CONCORD  
MP C19 H21 N3 O  
SR CA  
LC STN Files: CA, CAPLUS, USPATFULL



RN 220100-57-2 REGISTRY  
CN Spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridin]-5'-amine,  
N-(phenylmethyl)- (9CI) (CA INDEX NAME)  
FS 3D CONCORD  
MP C20 H23 N3 O  
SR CA  
LC STN Files: CA, CAPLUS, USPATFULL



Applicants' arguments have been considered but have not been found persuasive. As stated above, Phillips et al. teach spiroazabicyclic heterocyclic compounds that are structurally similar to the instant claimed compounds. Phillips et al. teach that the spiroazabicyclic heterocyclic compounds are useful in treating psychotic disorders. The compound in Phillips et al. found in column 3, lines 42-43 is the same compound found in the proviso at the end of instant claim 44. However, Phillips et al. teach that a group, such as a substituted amine group, represented by  $R^2$ ,  $R^3$  and  $R^4$  in Phillips et al. can be present not only at the 5-position of the spiroazabicyclic heterocyclic compound but also at the 4-position and the 6-position of the spiroazabicyclic heterocyclic compound as shown by the compounds in column 4, lines 37-40 in

Phillips et al. Therefore, a compound such as the last compound on page 6 of the Response filed June 30, 2004 (instant claim 55), would have been obvious to one skilled in the art.

*Allowable Subject Matter*

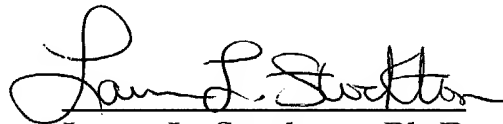
Claims 45, 46, 48, 50 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 57-69 are allowed over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, reading "Laura L. Stockton".

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 20, 2004